



Gluten Intolerance Group of NA
15110 – 10 Ave SW, Suite A
Seattle, WA 98166-1820

August 11, 2005

Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submit electronic comments to <http://www.fda.gov/dockets/ecomments>

Docket No. 2005N- 0279
Public Comment

The Gluten Intolerance Group of North America® (GIG) and its executive director, Cynthia Kupper, RD, CD, have been actively involved in advocacy efforts for effective labeling reform for allergens and gluten. GIG is pleased to be a part of the ongoing work by the FDA related to the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). In an ongoing effort to have the consumer's voice heard on questions in the upcoming August 19th, 2005 FDA meeting addressing Gluten-Free Labeling of Foods, an online consumer survey was conducted between July 29 and August 10, 2005. Announcements of the survey were posted to a number of celiac list serves, the Gluten Intolerance Group of NA (GIG) Web site and other supportive organization sites. An e-mail-tree was also set up to reach other consumers.

The online survey consisted of 17 questions derived from the consumer questions to be discussed at the Aug. 19, 2005, meeting of the Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) Docket No. 2005N-0279, 'Food Labeling; Gluten-Free Labeling of Foods; Public Meeting; Request for Comments.' The survey format includes single-answer, multiple-choice questions, and open-ended and essay questions.

The survey is biased toward Internet users who either visit celiac Web sites, list serves, or have provided e-mails to support groups; and have a stake in the topic due to having celiac disease or an association with someone who does. Therefore, it is not generalizable to the entire gluten-free community, but it does provide very important insights on gluten-free labeling issues. The survey tool used automatically compiles the raw data and provides a quick picture of the percentage of responses. The figures included here are preliminary and include only respondents from the USA. The study is being analyzed in greater depth.



Phone: 206-246-6652; Fax: 206-246-6531
www.gluten.net
info@gluten.net

Supporting persons with celiac disease, dermatitis herpetiformis and gluten intolerances, and health care professionals since 1974. GIG® is a 501c3 not-for-profit Washington State Corporation with Branches throughout the country.

Observation of internet list discussions and chat groups for celiac disease show that the range of knowledge and understanding of current issues related to labeling products gluten-free is variable. Quality of life studies have shown that issues related to food selection, availability, cost, and ability to determine a product's safety in the gluten-free diet negatively impact persons with celiac disease ⁽¹⁻⁴⁾. The purpose of this survey is to get the gluten-free consumer's perspective on the issues of labeling, purchasing decisions, and determination of what gluten-free means to consumers. The questions used in the survey are taken directly from the issues to be addressed at the August 19, 2005 HHS and FDA meeting.

Demographics

1,693 people from the USA participated in this survey, which had a total participation of 1976 respondents, at the time of this report, but now has nearly 2100 responses worldwide. Sixty-five percent of the participants (1,094/1,693) had biopsy-proven celiac disease (CD); 3 percent (44/1,693) had biopsy-proven dermatitis herpetiformis; 20 percent (336/1,693) had gluten intolerance (celiac disease diagnosed by other than the gold standard of a positive biopsy, or other forms of gluten intolerance, such as gluten ataxia), and the remaining 13% (219/1,693) were parents, spouses, caregivers, IgE allergic consumers, persons pending diagnosis, and other interested parties. The majority of those answering the survey were a) women, b) require gluten-free diet, c) primary shopper, d) primary decision-maker for what gluten free products are used, and e) primary cook (86%, 85%, 89%, 87%, and 81% respectively). More than half (963/1,679 or 57%) indicated they do not have other food intolerances or sensitivities.

Consumer Understanding of Current Labeling Practices for Gluten-Free

Consumers have mixed feelings and varying levels of understanding of the current labeling laws in the United States for gluten. Their interpretation of what grains and products constitute a "gluten-free" dietary pattern also varies. Some hold onto old beliefs about safety of certain products, while others openly embrace the idea of including products previously disallowed, such as vinegar and distilled products.

When asked, "What does the term 'gluten-free' mean to you?" responses varied to include: 'zero' (69%), 'no detectable gluten' (26%), 20 parts per million (ppm) (3%), 100 ppm (less than 1%), 200 ppm (less than 1%), and the 'Codex Alimentarius definition' (2%).

Likewise, the response to 'what is the current definition of "gluten-free" in the USA?' included a variety of answers. In this question, the respondent had to check 'Other' in order to indicate the correct answer. Using the same options in the previous question, plus a 'fill-in' option, responses included: 'zero' (25%), 'no detectable gluten' (31%), 20 ppm (11%), 100 ppm (3%), 200 ppm (4%), and the 'Codex Alimentarius definition' (4%). In the 'other' choice, 29% correctly indicated there is no current standard in the USA. The majority of respondents use the currently accepted definition that omits oats (74%) but a quarter of them are either unclear about oats or choose not to follow that definition ⁽⁴⁾.

To further address the issue of how the "gluten-free diet" is defined, respondents were asked if distilled products (alcohol-based extracts, distilled spirits and vinegar) are gluten-free. The majority said yes. (51% yes; 17% no; and 32% were unsure). Interestingly, while three-fourths of the participants use the older definition that excludes oats in a gluten-free diet, when asked, "If oats and wheat starch were tested and found to be gluten-free by a standard definition set (as a

result of research) by the FDA, would you include them in your diet?” 37% said yes, 29% no and 34% were unsure.

GF Consumer Shopping Practices

Gluten-intolerant consumers use a number of methods to determine gluten-free status and safety of food products they purchase. Nearly all (93%) read labels, but only 3% call manufacturers, and only 1% rely on product listings prepared by support groups and manufacturers. Still 25% only buy products labeled Gluten Free. Many consumers use a combination of these methods, while others rely on their gut reactions (or clinical symptoms). These same shoppers spend an average of 1-5 minutes (41%) determining if a product is gluten-free. When it includes purchasing foods for someone on a gluten-free diet, 46% and 39% respectively said they spend 30-60 minutes or 60-120 minutes per shopping trip.

Approximately 70% of consumers purchase up to 20% of their foods specifically labeled ‘gluten-free.’ Three-fourths (76%) of this same consumer include products labeled gluten-free in 5-50% of their total diet. The gluten-free labeled packaged products most often purchased include ready-made breads, cereals, cookies (82%); bread, cake and other mixes (61%); entrees – pizzas, shelf stable meals and soup cups (42%) and other products such as snack foods, special flours and baking supplies, nutritional supplements, energy bars, pasta, and canned soups and frozen entrees (45%). Consumers requiring gluten-free products are definitely influenced by a gluten-free label. The overwhelming majority, 86%, indicated that if two products have identical ingredients, they are extremely likely to choose a product labeled ‘gluten-free’ over one that is not labeled gluten-free.

Defining Gluten-Free for Product Labeling

At the July 13-15, 2005, proceedings of the FDA/CFSAN to assess the most appropriate methods for determining allergen thresholds, there was discussion amongst the panel of the possibility of a dual standard for gluten-free labeling. This discussion was initiated from the reports of Drs. P. Collin and A. Fasano⁽⁶⁻⁷⁾, in which they reviewed studies they had conducted to determine safe thresholds for gluten ingestion for persons with celiac disease. The Collin, et al study indicated 100-ppm gluten is safe, while the Fasano study recommended a threshold of 20 ppm as a safe level.

R. Kane of the CFSAN/FDA also reviewed the status of the Codex Alimentarius’ work on a revised definition for “gluten-free.” This discussion included the idea of a dual definition for gluten-free to possibly include a range from 20 ppm to 100 ppm, depending on the nature of the product being labeled. National consumer representatives in attendance at this meeting felt the gluten-free consumers would accept this type of definition as long as the definitions were very clear. However, this survey strongly suggests otherwise. Only 11% of the respondents in this survey would find a dual definition acceptable. Nearly half (47%) of the consumers were not in favor of dual definitions and 52% felt it would confuse them.

As further evidence that this dual definition would cause confusion, 42% felt they would not know how to determine if they could use the product, and 48% indicated they would be concerned that manufacturers and consumers would not know what definition is used in the labeling.

Consumers were offered the opportunity to share additional comments and thoughts. More than half (952/1693 OR 56%) added personal comments. These comments ranged from concerns about the FDA and manufacturers not fully understanding the consumer needs and concerns, to issues of cross-contact contamination; to persons expressing the need for more education themselves to be better educated on such matters, and a desire to see the labeling requirements expanded to include all ‘gluten’ sources of concern for persons with celiac disease.

Gluten-free is a term that is used worldwide to mean a safe product for consumption by persons with celiac disease. This term does not mean zero gluten in most countries. Consumers in the USA readily enjoy and accept products manufactured in Canada where the definition of gluten-free is less than 20 ppm.

Any term used other than ‘gluten-free’ to mean a safe product (no matter the final definition of ‘gluten-free’) has the high likelihood of causing confusion and increased mistrust by consumers. Such an example is a ‘low gluten communion host’ that has been determined to be safe for persons with celiac disease, yet is mistrusted because of the term ‘low gluten.’ We urge the FDA to consider that in terms of ‘gluten-free’, the word “free” must be redefined as something other than zero gluten.

We also encourage the FDA to consider the definition of ‘gluten’ to include the proteins from grains considered to be dangerous to persons with celiac disease – wheat, rye, barley and their hybrids, but to stop short of including oats. The evidence on oats indicates they are safe for consumption by the majority of persons with celiac disease ⁽⁸⁻¹⁴⁾. From this survey, it is also evident that at least 1/3 of persons with celiac disease would like to include oats in their diet, if they met a definition of ‘gluten-free.’ The inclusion of oats in the gluten-free diet also has health and compliance benefits, with the potential of improving the overall quality of life for persons with celiac disease ⁽¹⁵⁾. To date, companies in Canada and the USA are working to market ‘safe’ oats for a gluten-free diet, providing an alternative to having oats imported from other countries.

The Gluten Intolerance Group, on behalf of consumers encourages that a clear single definition for gluten-free be determined and that it be defined in a means by which manufacturers can comply. We thank you for your time and desire to hear the input of consumers. We welcome any opportunity to be a part of ongoing work in this area.

Sincerely,

Cynthia Kupper, RD, CD
Gluten Intolerance Group of North America

References

1. Hallert C, Granno C, Hulten S, Midhagen G, Strom M, Svensson H, Valdimarsson T. Living with coeliac disease: controlled study of the burden of illness. *Scand J Gastroenterol*. 2002 Jan;37(1):39-42.
2. Cranney A, Zarkadas M, Graham ID, Switzer C. The Canadian celiac health survey--the Ottawa chapter pilot. *BMC Gastroenterol*. 2003 May 11;3(1):8.
3. Lee A, Newman JM. Celiac diet: its impact on quality of life. *J Am Diet Assoc*. 2003 Nov;103(11):1533-5.
4. Case S.. The gluten-free diet: how to provide effective education and resources. *Gastroenterology*. 2005 Apr;128(4 Suppl 1):S128-34.
5. Manual of Clinical Dietetics 6th Edition, American Dietetic Association 2000.
6. Collin P, Thorell L, Kaukinen K, Mäki M. The safe threshold for gluten contamination in gluten-free products. Can trace amounts be accepted in the treatment of coeliac disease. *Aliment Pharmacol Ther* 2004; 19:1277-1283
7. Alessio Fasano, Carlo Catassi, Elisabetta Fabiani, Giuseppe Iacono, Ruggiero Francavilla, Cinzia D'Agate, Umberto Volta, Salvo Accomando, Antonio Picarelli Gino Roberto Corazza, Italo De Vitis, Giuseppe Nardone, Maria Teresa Bardella Italo Bearzi, Antonio Mandolesi. Toxicity Of Gluten Traces in Patients on Treatment for Celiac Disease. Results Of a Prospective, Placebo-Controlled, Double-Blind, Randomized Study. Abstract presentation at 2005 DDW
8. Janatuinen EK ; Kemppainen TA ; Julkunen RJ ; Kosma VM ; Mäki M ; Heikkinen M ; Uusitupa MI. No harm from five year ingestion of oats in coeliac disease. *Gut (Gut.)* 2002 Mar; 50(3): 332
9. Peraaho M, Kaukinen K, Mustalahti K, et al. Effect of an oats-containing gluten-free diet on symptoms and quality of life in celiac disease: a randomized study. *Scand J Gastroenterol* Jan; 2004; 39: 27-31.
10. Størsrud S ; Hulthén LR ; Lenner RA . Beneficial effects of oats in the gluten-free diet of adults with special reference to nutrient status, symptoms and subjective experiences. *Br J Nutr*. 2003 Jul; 90(1): 101-7
11. Storsrud S, Olsson M, et al. Adult celiac patients do tolerate large amounts of oats. *Eur J Clin Nutr* 2003 Jan; 57 : 163-169
12. Reunala, T, Collin P, Holm K, et al. Tolerance to oats in dermatitis herpetiformis. *Gut* 1998; 43: 490-493.
13. Hoffenberg EJ, Haas J, Drescher A, Barnhurst R, Osberg I, Bao F, Eisenbarth G. A Trail of Oats in Children with Newly diagnosed Celiac Disease. *J Pediatr*. 2000; 137:361-366.
14. Höberg L, Laurin P, Fälth-Magnusson K, Grant C, Grodzinsky E, Jansson G, Ascher H, Browaldh L, Hammersjö JA, Lindberg E, Myrdal U, Stenhammar L. Oats to children with newly diagnosed coeliac disease: a randomized double-blind study. *Gut* 2004; 53:649-654.
15. Kupper C. Dietary guidelines and implementation for celiac disease. *Gastroenterology*. 2005 Apr;128(4 Suppl 1):S121-7.

On-line Survey

FDA Gluten-Free Labeling

[Exit this survey >>](#)

The FDA is in the process of determining a number of factors related to allergen labeling issues. One issue of significance to the gluten-free consumer is how the term gluten-free will be used on labels.

I shared the results of a consumer survey conducted in March with the FDA. They want to hear more from you. Please take a few minutes to answer these questions. This information will be reported to the FDA, as part of a meeting on August 19, 2005.

Thank You.

Cynthia Kupper, RD, CD
Gluten Intolerance Group of NA

Online Consumer Survey

2. Untitled Page

1. Do you have:

- ☐ A) Celiac Disease (biopsy proven)
- ☐ B) Dermatitis Herpetiformis (biopsy proven)
- ☐ C) Gluten Intolerance
- ☐ Other (please specify)

2. Do you have other food intolerances or sensitivities?

- ☐ A) Yes
- ☐ B) No

3. Tell us about yourself.

- ☐ A) Male

- ☐ B) Female
- ☐ C) Person requiring gluten free diet
- ☐ D) Support person needing gluten free diet
- ☐ E) Primary gluten free food purchaser
- ☐ F) Primary decision maker about what gluten free products are used
- ☐ G) Primary cook
- ☐ H) I am a USA resident

4. What does the term "gluten-free" mean to you?

- ☐ A) Zero gluten
- ☐ B) No detectible gluten
- ☐ C) 20 ppm
- ☐ D) 100 ppm
- ☐ E) 200 ppm
- ☐ F) Codex Alimentarius definition

5. What is the current definition of "gluten free" in the USA?

- ☐ A) Zero gluten
- ☐ B) No detectible gluten
- ☐ C) 20 ppm
- ☐ D) 100 ppm
- ☐ E) 200 ppm
- ☐ F) Codex Alimentarius definition

☐ Other (please specify)

6. What does it mean to you when products are labeled gluten free?

- ☐ A) contains no wheat, rye or barley
- ☐ B) contains no wheat, rye, barley or oats
- ☐ C) A above plus products made from them, such as wheat starch
- ☐ D) B above plus products made from them, such as wheat starch or oat gum
- ☐ Other (please specify)

7. Distilled products (alcohol-based extracts, distilled spirits and vinegar) are gluten-free?

- ☐ A) yes
- ☐ B) no
- ☐ C) unsure

8. In your opinion, if oats and wheat starch were tested and found to be gluten-free by a standard definition set (as a result of research) by the FDA, would you include them in your diet?

- ☐ A) yes
- ☐ B) no
- ☐ C) unsure

9. How do you determine if a product is gluten free?

- ☐ A) read labels

- ☐ B) call manufacturer
- ☐ C) rely on product lists prepared by celiac support groups or the manufacturer
- ☐ D) use only products labeled gluten-free
- ☐ Other (please specify)

10. On average, how much time do you spend determining if a product is gluten free and safe to use?

- ☐ A) 1-5 minutes
- ☐ B) 6-10 minutes
- ☐ C) Up to 30 minutes
- ☐ D) Over 30 minutes

11. How long does your average shopping trip take, when purchasing foods for a person on a gluten-free diet?

- ☐ A) Less than 30 minutes
- ☐ B) 30 minutes to 1 hour
- ☐ C) 1-2 hours
- ☐ D) More than 2 hours

12. What percentage of the packaged foods that are purchased for the consumer needing a gluten free diet are labeled 'gluten free'?

13. What percentage of the gluten free consumer's total diet is composed of products labeled 'gluten free'?

14. What types of packaged foods labeled 'gluten free' do you most often purchase?

- ☐ 1) already made breads, cookies, cereals
- ☐ 2) mixes for breads and cookies
- ☐ 3) entrees – pizzas, shelf stable meals and soup cups
- ☐ 4) other specialty products
- ☐ Other (please specify)

15. If two products are identical, how likely are you to choose a product labeled 'gluten-free' over one not labeled gluten free?

- ☒ 1) Extremely likely
- ☐ 2) very likely
- ☐ 3) somewhat likely
- ☐ 4) not likely
- ☐ 5) highly unlikely
- ☐ Other (please specify)

16. A dual definition may be considered for use to define 'gluten free' products. An example might be: 20 ppm for products using naturally gluten-free ingredients AND 100 ppm for products using ingredients rendered 'gluten free' or substituted to make a product 'gluten free.'

How would you feel about the use of this type of definition for gluten free?

- ☐ A) This would be ok, as long as it was clear what the definition is and how it is to be used.

- ☐ I would not be in favor of dual definitions for gluten free
- ☐ B) It would be confusing to me
- ☐ C) I would not know how to determine if I could use the product
- ☐ D) I would be concerned manufacturers and consumers would not know what definition to use in labeling.

17. Please share with us any other thoughts or comments you would like to add.



Thank you for participating in this survey. Your feedback is important and valuable.